

§ 107.2

9 CFR Ch. I (1–13 Edition)

(i) The veterinarian has assumed the responsibility for making medical judgments regarding the health of the animal(s) and the need for medical treatment, and the client (owner or other caretaker) has agreed to follow the instructions of the veterinarian; and when

(ii) There is sufficient knowledge of the animal(s) by the veterinarian to initiate at least a general or preliminary diagnosis of the medical condition of the animal(s). This means that the veterinarian has recently seen and is personally acquainted with the keeping and care of the animal(s), and/or by medically appropriate and timely visits to the premises where the animal(s) are kept; and when

(iii) The practicing veterinarian is readily available for followup in case of adverse reactions or failure of the regimen.

(2) Veterinarians preparing products subject to the exemption for products under this section shall maintain and make available for inspection by Animal and Plant Health Inspection Service representatives or other Federal employees designated by the Secretary such records as are necessary to establish that a valid veterinarian-client-patient relationship exists and that there is a valid basis for the exemption under this section.

(b) Products prepared by a person solely for administration to animals owned by that person shall be exempt from the requirement that preparation be pursuant to an unsuspended and unrevoked license.

[52 FR 30131, Aug. 13, 1987, as amended at 56 FR 66783, Dec. 26, 1991]

§ 107.2 Products under State license.

(a) The Administrator shall exempt from the requirement of preparation pursuant to an unsuspended and unrevoked USDA establishment and product license, any biological product prepared solely for distribution within the State of production pursuant to a license granted by such State under a program determined by the Administrator to be consistent with the intent of the Act to prohibit the preparation, sale, barter, exchange, or shipment of worthless, contaminated, dangerous, or harmful biological products.

(b) A request for exemption under this section must be made by the appropriate State authority and shall include information demonstrating that:

(1) The State has the authority to license viruses, serums, toxins, and analogous products and establishments that produce such products; and

(2) The State has the authority to review the purity, safety, potency, and efficacy of such products prior to release to the market; and

(3) The State has the authority to review product test results to assure compliance with applicable standards of purity, safety, and potency prior to release to the market; and

(4) The State has the authority to deal effectively with violations of State law regulating viruses, serums, toxins, and analogous products; and

(5) The State effectively exercises the authority specified in paragraphs (b)(1) through (4) of this section consistent with the intent of the Act prohibiting the preparation, sale, barter, exchange, or shipment of worthless, contaminated, dangerous, or harmful viruses, serums, toxins, or analogous products.

(c) Each product to be exempted and each establishment preparing such product shall be identified by the State and the State shall give written notification to the Administrator of each such product and establishment. The State shall also give written notice to the Administrator of each new license issued and of each license terminated.

(d) In order to determine whether a State exercises its authority with respect to biological products and establishments and whether its laws and regulations are being achieved, the Administrator, in cooperation with proper State authorities, may conduct an on-site evaluation of the State's program which may include inspection of establishments and/or products to be included under the exemptions in this section.

[52 FR 30131, Aug. 13, 1987, as amended at 56 FR 66783, Dec. 26, 1991]

PART 108—FACILITY REQUIREMENTS FOR LICENSED ESTABLISHMENTS

Sec.

108.1 Applicability.